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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,685	11/07/2000	Julio C. Palmaz	6006-015	9696

7590

07/17/2003

David G Rosenbaum
Rosenbaum & Associates PC
875 North Michigan Ave
Suite #3653
Chicago, IL 60611

EXAMINER

MILLER, CHERYL L

ART UNIT PAPER NUMBER

3738

15

DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

Office Action Summary	Application No.	Applicant(s)	
	09/707,685	PALMAZ ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 18-20, 23, 29-33 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 18-20, 23, 29-33 and 35-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7, 11</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 2, 2003 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 14-23 and 29-38 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14, 19, 29, 30, 33, and 35-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Clubb et al. (USPN 6,203,732 B1, cited in a previous office action).

Referring to claim 14, Clubb discloses a method of manufacturing a stent (col.1, lines 6-10) having a plurality of first structural elements (106) defining a longitudinal axis and a plurality of second structural elements (104) interconnecting adjacent pairs of first structural elements (fig.17), comprising providing a generally cylindrical unpatterned metal substrate (10,

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fig. 1, 2) having a continuously curved exterior surface, vacuum depositing a metal (100) onto the exterior metal surface (12) of the substrate (fig. 13, 14), defining the plurality of first and second structural elements (104, 106) in the stent forming metal (by removal of excess material fig. 15, 16), and removing the substrate from the stent (col. 2, lines 25-36; fig. 17, 18).

Referring to claim 19, Clubb discloses vacuum deposition of metal by sputtering (col. 5, lines 35-47).

Referring to claim 29, Clubb discloses a method of manufacturing a stent (col. 1, lines 6-10) having a plurality of first structural elements (106) defining a longitudinal axis and a plurality of second structural elements (104) interconnecting adjacent pairs of first structural elements (fig. 17), comprising providing a generally cylindrical unpatterned metal substrate (10, fig. 1, 2) having a continuously curved exterior surface, vacuum depositing a metal (100) onto the exterior metal surface (12) of the substrate (fig. 13, 14), forming the plurality of first and second structural elements (104, 106) in the stent forming metal (by removal of excess material fig. 15, 16), and removing the substrate from the stent (col. 2, lines 25-36; fig. 17, 18).

Referring to claim 30, Clubb discloses vacuum deposition of metal by sputtering (col. 5, lines 35-47).

Referring to claim 33, Clubb discloses a stent forming metal (100) selected from the group of titanium, tantalum, zirconium, niobium, or platinum (col. 5, lines 21-24).

Referring to claims 35-38, Clubb discloses control of the formation of heterogeneities in the stent forming metal (col. 5, lines 12-20, Clubb discloses controlling the type of material, combination of materials, size and thickness of material used during deposition, therefore,

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heterogeneities in the surfaces of the material are controlled, in addition, because the method of Clubb is the same as the applicants, the material properties will inherently be the same.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 18-20, 23, 29-33, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth (USPN 6,096,175, cited in a previous office action) in view of Clubb et al. (USPN 6,203,732 B1, cited in a previous office action). Referring to claims 14 and 29, Roth discloses a method of making a stent (col.1, lines 4-6) having a plurality of first structural elements (32) defining a longitudinal axis and a plurality of second structural elements (26, 27, 28) interconnecting adjacent pairs of first structural elements (fig.2), comprising providing an unpatterned metal substrate (36), vacuum depositing a stent forming metal (56) onto the exterior surface of the substrate (fig.6, step C), defining the plurality of first and second structural elements of the stent in the stent forming metal (fig.6, step C,D), and removing the substrate (36) from the stent (56, fig.6 step E; col.10, lines 33-46). Roth discloses a method similar to the claimed method, however uses a flat substrate instead of a cylindrical substrate. Clubb teaches in the same field of stent manufacturing, a method of making a stent by vacuum deposition, by vacuum depositing metal (100) onto a cylindrical substrate (10), for the purpose of making cylindrical articles which conform to the shape of the substrate and are shape ready for implantation (col.2, lines 25-33; col.3, lines 15-17). If not an obvious design choice of shape, it

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would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Roth's stent manufacturing method, with Clubb's teaching of using a cylindrical substrate in such methods, in order to manufacture a cylindrical stent.

Referring to claims 18-20, 23, and 30, Roth discloses vacuum deposition by ion beam evaporation or sputtering, wherein the evaporation is in the presence of an inert gas selected from the group of argon, xenon, nitrogen and neon (col.5, lines 25-40; col.6, lines 19-23).

Referring to claims 31-33, Roth discloses the stent forming metal being a binary nickel titanium shape memory alloy, or other metals (col.4, lines 18-20).

Referring to claims 35-38, Roth discloses control of the formation of heterogeneities in the stent forming metal (col.6, lines 10-15, Roth discloses controlling the type of material, combination of materials using multiple targets, size and thickness of material used during deposition, therefore, heterogeneities in the surfaces of the material are controlled, in addition, because the method of Roth is the same as the applicants, the material properties will inherently be the same).

In an alternative to the above rejection, claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth (USPN 6,096,175, cited in a previous office action) in view of Clubb et al. (USPN 6,203,732 B1, cited in a previous office action) as applied to claim 29 above, and further in view of Busch et al. (USPN 5,061,914, cited by applicant in IDS). Roth in view of Clubb discloses a method of manufacturing a stent as claimed (see above). Roth does disclose control of the type of material used, combination of materials using multiple targets, size and thickness of material used during deposition (col.6, lines 10-15), however does not explicitly disclose that these variations are controlling heterogeneities in the metal during deposition.

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Busch teaches in the related art of vacuum deposition of microactuators (Roth discloses acknowledgement of similar alloyed vacuum deposition processes in the related art of microactuators col.2, lines 52-55) vacuum deposition processes (col.3, lines 30-32) similar to the process of Roth, using the same alloyed metals as Roth and Busch teaches vacuum deposition of such metals in order to control the heterogeneities of the metal, which precisely controls the metal composition and crystal structure therefore creating the desired material properties (col.7, lines 50-58; col.8, lines 30-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Roth in view of Clubb's vacuum deposition method to make a stent, the teaching of Busch that vacuum deposition such as sputtering causes control of heterogeneities of the metal used, in order to have precise control over the metal composition and material properties.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Cheryl Miller
July 16, 2003


BRUCE SNOW
PRIMARY EXAMINER